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| EXAMINER | |
|---|---|
| CWERN, JONATHAN | |
| ART UNIT | PAPER NUMBER |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/764,010 | ALEXANDER ET AL. | |
| | Examiner | Art Unit | |
| | Jonathan G. Cwern | 3737 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *09 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,7,10,15,18-22,55-61,66-71,85,86,94-153,190 and 228-256* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,7,10,15,18-22,55-61,66-71,85,86,94-153,190 and 228-256* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 7, 10, 15, 153, and 190 are rejected under 35 U.S.C. 102(e) as being anticipated by Ateshian et al. (US 6126690).

Ateshian et al. disclose an anatomically correct prosthesis and method and apparatus for manufacturing prosthesis. Ateshian show obtaining image data of the surface of a joint, modifying the image data to provide a more functional surface topography, and the fabricating a joint prosthesis. Also, image data of a healthy joint can be obtained and used to fabricate a prosthesis for a similar diseased joint (column 6, lines 20-32). The prosthesis is composed of head surfaces with each surface having an anatomically accurate shape (column 5, lines 35-40). Furthermore, the image data can be obtained by MRI, CT, or stereophotogrammetry methods (column 7, lines 20-39; column 11, line 20-column 12, line 57). These imaging techniques will obtain data of the joint, such as cartilage and subchondral bone properties.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 10, 15, 18-19, 21-22, 55-58, 60-61, 66-71, 85-86, 94-152, and 228-256 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ateshian et al. (US 6126690) in view of Aouni-Ateshian et al. (US 6161080), Delp et al. (US 5682886), Paul et al. (US 5320102), and Goldberg et al. (US 6835377).

Ateshian et al. disclose an anatomically correct prosthesis and method and apparatus for manufacturing prosthesis. Ateshian show obtaining image data of the surface of a joint, modifying the image data to provide a more functional surface topography, and the fabricating a joint prosthesis. Also, image data of a healthy joint

can be obtained and used to fabricate a prosthesis for a similar diseased joint (column 6, lines 20-32). The prosthesis is composed of head surfaces with each surface having an anatomically accurate shape (column 5, lines 35-40). Furthermore, the image data can be obtained by MRI, CT, or stereophotogrammetry methods (column 7, lines 20-39; column 11, line 20-column 12, line 57). These imaging techniques will obtain data of the joint, such as cartilage and subchondral bone properties. However Ateshian et al. fail to explicitly describe using cartilage data to aid in the implant construction, analyzing degenerative cartilage in the patient, and estimating gait.

Aouni-Ateshian et al. disclose a method of generating a three-dimensional representation of one or more anatomical joints. Aouni-Ateshian et al. teach that cartilage topography and thickness can be reconstructed, and geometric data needed for a model can be obtained (column 37, line 65-column 8, line 25). Also, that such a model can be used for designing prostheses (column 1, lines 59-65).

When designing a model to analyze an object, it is typical to design the model as close to the real object as possible, in order to accurately analyze what would happen to the real object. Therefore, it is obvious that the physical model would reflect the patient's anatomy, such as the geometry and thickness of the normal and diseased cartilage, and the inner and outer surfaces, and the subchondral bone. Of course, nearly any surface can be considered either an inner or an outer surface depending on one's point of view.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have considered the cartilage surface when designing the

prosthesis in Ateshian et al. as taught by Aouni-Ateshian et al. While Ateshian et al. only refer to the joint surface, one of ordinary skill in the art is aware that this would include both articular cartilage as well as subchondral bone, and it would be obvious to take into account all parts of the joint when designing an anatomically correct implant, as this will increase the accuracy of the design.

When designing such an implant, it is of course necessary for it to reflect the proportions of the body part being replaced so that it will fit appropriately within the patient. Therefore, at least a portion of the implant would have thickness similar to that of normal articular cartilage adjacent to diseased articular cartilage.

Paul et al. disclose a method of treating a human with diseased cartilage in a joint. Paul et al. teach a method of treating a human with diseased cartilage in a joint (abstract), which method comprises: utilizing an MRI scan to generate a cross-sectional electronic image of said joint (column 4, lines 1-55), wherein said image includes both normal and diseased cartilage (column 10, lines 55-65); and utilizing information from said image to create a geometric model of an area of diseased cartilage (the MR cartilage image is a model, column 4, lines 55-65), wherein said geometric model is used in selecting a treatment of said diseased cartilage (column 11, lines 35-55); electronically evaluating the image of the joint to determine the thickness or biochemical content (column 4, lines 1-10, and column 5, line 65-column 6, line 5); obtaining a three-dimensional map (the MR cartilage image is a three-dimensional map, column 4, lines 55-65); determining the margins of the diseased cartilage in relation to the normal cartilage based on the thickness or biochemical contents, allowing for the area of

diseased cartilage to be calculated (the MRI scan of the joint allows for the total cartilage surface area to be determined, knowledge of the margins of the diseased area will then allow for a calculation of the total area of the joint containing diseased cartilage, column 10, lines 55-65). Also, estimating the change in thickness of a region of the cartilage over time to determine a change in thickness between a first time and a second time, to determine the amount of degeneration in the cartilage (column 11, lines 5-55); the therapy includes an agent that stimulates repair of diseased tissue (column 11, lines 45-55); the MRI technique obtains a series of two-dimensional views reconstructed to a three-dimensional image (implicit with MR imaging); the MRI technique employs gradient or spin echo (column 4, lines 25-40). Data transmission throughout a computer system is well known in the art, any part of the computer can be considered a "site" or the receiving or transmitting device, and the term "located distant" can refer to any distance.

It would have been obvious to one of ordinary skill in the art, to analyze the degenerative cartilage in the patient and to have determined a therapy based on the cartilage information as taught by Paul et al., in the prosthesis design of Ateshian et al., in order to better develop a proper implant.

Delp et al. show a system for joint replacement surgery. The system processes medical image data to build a 3D computer model of the patient's leg, and align, size, and place a prosthetic component (column 8, lines 5-31). The three-dimensional geometry of the joint is analyzed to determine the required dimensions and geometry of the prosthesis. A number of points are selected in the 3D surface reconstruction of the

joint and prosthesis (column 9, line 19-column 11, line 5). Selecting points in three-dimensional space in order to develop the proper dimensions and geometry of a three-dimensional object would inherently include determining three non-coplanar points. Points would be selected on the different bones of the joint, such as in the case of a knee joint, the lateral or medial femoral condyle (column 7, lines 38-52). A variety of different imaging modalities can be used to obtain the data (column 8, lines 32-61). The biomechanical information, such as the biomechanical axes, is obtained (column 11, lines 49-59) and used when designing the model, as well as anatomical information such as anatomical landmarks (column 11, lines 25-27). The contact surfaces are accounted for as well (column 14, lines 1-42). By utilizing constraints, both static and dynamic alignment are accounted for, in order to ensure that there is equal contact throughout the range of motion and to prevent the ligaments from being too tight in extension. Estimating for normal gait is an obvious modification, as gait is a typical unconstrained movement, and would be accounted for when ensuring equal contact throughout the range of motion.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have used a planning system to properly place the prosthesis and aid in the design of the prosthesis of Ateshian et al. This will provide a more accurate prosthesis by taking into account a variety of other patient specific parameters such as gait.

Goldberg et al. disclose a method for repair of degenerative cartilage. Goldberg et al. teach that the therapy can comprise osteotomy or an autologous chondrocyte

transplantation (it is well known to perform osteotomy, column 1, lines 40-50, also the method used in the invention uses autologous mesenchymal stem cells supported by a three-dimensional scaffold, which is implanted in the body, column 3, lines 1-25).

It would have been obvious to one of ordinary skill in the art, to have implanted a device as taught by Goldberg et al. in place of the prosthesis implanted by Ateshian et al. in order to aid in repairing the degenerated cartilage.

Claims 20 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ateshian et al. (US 6126690) in view of Aouni-Ateshian et al. (US 6161080), Delp et al. (US 5682886), Paul et al. (US 5320102), and Goldberg et al. (US 6835377) as applied to claims 1 and 10 above, and further in view of George, III et al. (US 6175655).

George, III et al. disclose a method for manipulating 3D MRI data to view internal body structure. George, III et al. teach the use of 3D Euclidean distance values in manipulating the 3D MRI data (table of column 8-column 9 shows a variable used which is Euclidean distance between points).

The Euclidean distance is a well known technique to calculate the distance between two points, and could be used when constructing the 3D model.

***Response to Arguments***

Applicant's arguments with respect to claims 1, 7, 10, 15, 18-22, 55-61, 66-71, 85-86, 94-153, 190, and 228-256 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Tubo et al. (US 5786217) and (US 5723331), Draenart (US 554190), Johnson (US 5609640), Kennedy (US 5360446), Berchem et al. (US 5150304), Mendes et al. (6102955), Reuben (5448489), and Walker et al. (4822365). Tubo et al. discloses methods for repairing articular cartilage by implanting synthetic cartilage into the diseased site, as well as designing the appropriately sized cartilage for replacement. Other references are directed towards the design of patient specific joint implants with data obtained by imaging the diseased joint.

These references are provided in view of the examiner's discussion during the interview conducted 9/10/09. Applicant's appeared to distinguish their invention over other prior art implants by indicating that their implant was designed based upon actual imaged data of the specific patient. The above references are provided to demonstrate a variety of different patient specific joint implants based on image data of the joint which are known in the art, to aid applicant in further amending the claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan G. Cwern whose telephone number is (571)270-1560. The examiner can normally be reached on Monday through Friday 9:30AM - 6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jonathan G Cwern/
Examiner, Art Unit 3737

/BRIAN CASLER/
Supervisory Patent Examiner, Art Unit 3737